K042415

JUN 9 - 2005

Summary of Safety and Effectiveness

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Trade Name: Mendec Spine

Common Name: Bone Cement

Classification Name: Bone Cement, 888.3027

Device code: NDN, LOD

Manufacturer/Submitter: TECRES S.p.A FDA Owner number: 9033624
Via Andrea Doria 10,
37066 Sommacampagna, Verona, Italia
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Contact person: Massimo Grazioli, General Manager

Predicate device:

K033801:	Kyphx HV-R Bone Cement (Kyphon Inc.).
K041584:	Kyphx HV-R Bone Cement (Kyphon Inc.).
K032945:	Stryker Spineplex Radiopaque Bone Cement (Stryker)

Indications for use: Mendec Spine is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, bening lesions (hemangioma), and malignant lesions (metastatic cancers, mylema)

Device Description: Like the predicate devices , Mendec Spine acrylic resin is provided as a two-component system. The powder component consists of a PMMA-styrene copolymer with barium sulphate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer, with the addition of hydroquinone as a stabiliser aqnd N,N-dimethyl-p-toluidine as promoter. The powder and liquid components are mixed prior to

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use. Table 4-1 compares the chemical composition of Mendec Spine to the predicate device.

Table 4-1 Chemical composition of Mendec Spine and Kyphx HV-R

Chemical composition	***KyphX HV-R*** #K033801 #K041584	***Spineplex*** #K032945	***Mendec Spine***
Powder	**20 g**	**20 g**	**20 g**
Polymethymethacrylate	68,0% w/w	68,50% w/w	67,50% w/w
Barium sulphate	30,0% w/w	30,0% w/w	30,0% w/w
Benzoyl peroxide	2,0% w/w	1,5% w/w	2,5% w/w
Liquid	**9 g**	**9.96 ml (9.05 g)**	**9.4 g**
Methylmethacrylate (monomer)	99,1% w/w	97,4% w/w	99,1% w/w
N,N-dimethyl-p-toluidine	0,90% w/w	2,60% w/w	0,90% w/w
Hydroquinone	75 ppm	75 ppm	75 ppm

Mechanical tests: Mendec Spine acrylic resin was tested in direct comparison to the predicate device and verified substantially equivalent, as defined by ISO 5833:2002, "Implants for Sugery – Acrylic resin cements"

Non-clinical test results: Performance testing demonstrated that Mendec Spine is substantially equivalent to the Kyphx HV-R with regard to functional characteristics

Clinical results: Clinical information demonstrates that the intended use is substantially equivalent to the predicate indication for the treatment of pathological vertebral body fractures and does not adversely impact safety and effectiveness.

Biocompatibility: The materials used in Mendec Spine complies with ASTM F 451-99 point 10 and ISO 10993

Sterilization: The Mendec Spine acrylic resin is sterile and non-pyrogenic. The solid components are sterilised with ethylene oxide (EO) gas to a Sterility Assurance Level (SAL) of 10^{-6}. The liquid components are sterilized with filtration methods to a SAL of 10^{-3}. The outer packaging containing the liquid component is sterilised with ethylene oxide (EO) gas. The acrylic resin is intended for single use only.

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Substantial Equivalence: The chemical constituents in Mendec Spine acrylic resin are substantially equivalent to those in the predicates Kyphx HR-V (#K033801; #K041584) and in the predicate Spineplex (#K032945).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tecres Spa
C/o Christine L. Brauer, Ph.D
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
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Bethesda, Maryland 20817

Re: K042415
Trade/Device Name: Mendec Spine
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: May 18, 2005
Received: May 18, 2005

Dear Dr. Brauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042415

Device Name: Mendec Spine

Indications For Use:

Mendec Spine is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporesis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042415